

**UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TENNESSEE
KNOXVILLE DIVISION**

ABRA L. CONING,)
)
)
Plaintiff,)
)
)
v.)
)
BAYER HEALTHCARE)
PHARMACEUTICALS INC.,)
BAYER PHARMA AG, and)
BAYER OY,)
)
)
Defendants.)
)

)

CASE NO. 3:15-cv-00137-PLR-HBG

**LIST OF EVIDENTIARY MATERIALS RELIED UPON BY DEFENDANTS IN
SUPPORT OF DEFENDANTS' OMNIBUS MOTION TO EXCLUDE THE GENERAL
CAUSATION AND LABELING OPINIONS OF PLAINTIFF'S EXPERTS**

Defendants Bayer HealthCare Pharmaceuticals Inc., Bayer Pharma AG, and Bayer Oy (collectively, “Bayer”) submit the following evidentiary materials in support of their Omnibus Motion to Exclude the General Causation and Labeling Opinions of Plaintiff’s Experts:

Exhibit:

1. May 19, 2009 health record from Dr. Geoffrey C. Kincaid (FSOBGYNG-000079)
2. Excerpts from Deposition of Abra Coning (“Coning Dep.”)
3. August 14, 2013 health record from Dr. Timothy K. Braden (FSRMC-000036 to -037)
4. Alison Edelman & Bliss Kaneshiro, *Contraceptive Counseling for Obese Women*, UpToDate (2016)

5. CDC, *U.S. Medical Eligibility Criteria for Contraceptive Use*, 59 Morbidity & Mortality Wkly. Rep. RR-4 (2010)
6. Mary L. Marnach et al., *Current Issues in Contraception*, 88 Mayo Clinic Proc. 295 (2013)
7. October 4, 2016 Deposition of Axel Rosengart (“Rosengart 10/4/16 Dep.”)
8. Expert Report of Frederick Fraunfelder (“Fraunfelder Report”)
9. Deposition of David Ross (“Ross Dep.”)
10. Anthony B. Daniels et al., *Profiles of Obesity, Weight Gain, & Quality of Life in Idiopathic Intracranial Hypertension (Pseudotumor Cerebri)*, 143 Am. J. Ophthalmology 635 (2007)
11. Lynne Y. Saito-Tom et al., *Levonorgestrel Intrauterine Device Use in Overweight and Obese Women*, 74 Haw. J. Med. & Pub. Health 369 (2015)
12. March 25, 2009 health record from Allergy & Asthma Associates (FSRMC-000003 to -015)
13. December 9, 2016 Deposition of Axel Rosengart (“Rosengart 12/9/16 Dep.”)
14. August 14, 2013 health record from Dr. Timothy K. Braden (AAA-000051 to -053)
15. Minutes of the 106th Medicines Adverse Reactions Committee Meeting (Paul Korner Dep. Ex. 16)
16. April 4, 2008 Letter from the UK Medicines and Healthcare Products Regulatory Agency to Bayer (MIR_JSEU_780138)
17. Deposition of Mahyar Etminan (“Etminan Dep.”)

18. Notices of Withdrawal of Expert Witness filed in *Bridges v. Bayer*, *Cheek v. Bayer*, *Copley v. Bayer*, *Hoover v. Bayer*, *Kellington v. Bayer*, and *Sellers v. Bayer* (“Etminan Notices of Withdrawal”)
19. December 12, 2016 Affidavit of Dr. Mayhar Etminan (“Etminan Aff.”)
20. Memorandum Opinion and Order, *Kellington v. Bayer Healthcare Pharms., Inc.*, No. 5:14-cv-00002 (W.D. Va. Aug. 16, 2016) (ECF No. 155)
21. FDA, “Readme.doc” File for the Quarterly Data Extract from FAERS (Etminan Dep. Ex. 12)
22. Expert Report of John Maggio (“Maggio Report”)
23. Expert Report of David Ross (“Ross Report”)
24. Deposition of Frederick Fraunfelder (“Fraunfelder Dep.”)
25. Raju Rai et al., *The Relationship Between the Levonorgestrel-Releasing Intrauterine System & Idiopathic Intracranial Hypertension*, ARVO Annual Meeting Abstracts (2015)
26. A.J. Sunku et al., *Benign Intracranial Hypertension Associated with Levonorgestrel Implants*, 34 Annals Neurology 299 (1993)
27. John B. Alder et al., *Levonorgestrel Implants and Intracranial Hypertension*, 332 New Eng. J. Med. 1720 (1995)
28. Diane K. Wysowski & Lanh Green, *Serious Adverse Events in Norplant Users Reported to the Food and Drug Administration’s MedWatch Spontaneous Reporting System*, 85 Obstetrics & Gynecology 538 (1995)
29. Michael Wall, *Idiopathic Intracranial Hypertension*, 28 Neurologic Clinics 593 (2010)

30. Alex K. Ball & Carl E. Clarke, *Idiopathic Intracranial Hypertension*, 5 Lancet Neurology 433 (2006)
31. Reuben M. Valenzuela et al., *Exploratory Study of the Relationship Between the Levonorgestrel-Releasing Intrauterine System and Idiopathic Intracranial Hypertension*, NANOS Annual Meeting Posters (2015)
32. Expert Report of Axel Rosengart (“Rosengart Report”)
33. Chapter 86 of Geraldine Siena L. Mariano, Matthew E. Fink, Caitlin Hoffman, & Axel Rosengart, *Principles of Critical Care* (4th ed. 2015) (Rosengart 10/4/16 Dep. Ex. 19)
34. Excerpt of September 13, 2016 Deposition of Rosa Tang (“Tang 9/13/16 Dep.”)
35. Deposition of John Maggio (“Maggio Dep.”)
36. Mahyar Etminan et al., *Risk of Intracranial Hypertension with Intrauterine Levonorgestrel*, 6 Therapeutic Advances Drug Safety 110 (2015)
37. F. Jane Durcan et al., *The Incidence of Pseudotumor Cerebri: Population Studies in Iowa and Louisiana*, 45 Archives Neurology 875 (1988)
38. Vincent Giuseffi et al., *Symptoms and Disease Associations in Idiopathic Intracranial Hypertension (Pseudotumor Cerebri): A Case-Control Study*, 41 Neurology 239 (1991)
39. Kurupath Radhakrishnan et al., *Epidemiology of Idiopathic Intracranial Hypertension: A Prospective and Case-Control Study*, 116 J. Neurological Sci. 18 (1993)
40. Belinda Ireland et al., *The Search for Causes of Idiopathic Intracranial Hypertension: A Preliminary Case-Control Study*, 47 Archives Neurology 315 (1990)

41. FDA, *Guidance for Industry: Good Pharmacovigilance Practices* (2005)
42. Jagger C. Koerner et al., *Inpatient and Emergency Service Utilization in Patients with Idiopathic Intracranial Hypertension*, 34 J. Neuro-Ophthalmology 229 (2014)
43. Clinical Trial Cases (Ross Ex. 28)
44. Haydée Martínez et al., *Atypical Pseudotumor Cerebri*, 34 Neuro-Ophthalmology 255 (2010)
45. “Rechallenge” Case (Ross Dep. Ex. 29)
46. Frederick T. Fraunfelder et al., *Drug-Induced Ocular Side Effects* (7th Ed. 2015) (Fraunfelder Dep. Ex. 14)
47. Ruwen Böhm, *Primer on Disproportionality Analysis* (2015) (Etminan Dep. Ex. 11)
48. S. J. W. Evans et al., *Use of Proportional Reporting Ratios (PRRs) for Signal Generation from Spontaneous Adverse Drug Reaction Reports*, 10 Pharmacoepidemiology & Drug Safety 483 (2001)
49. OpenVigil Homepage (Etminan Dep. Ex. 10)
50. OpenVigil Cave-at Document (Etminan Dep. Ex. 17)
51. Medical Economics Co., *Physician’s Desk Reference* (1996) (“1996 Norplant Label”)
52. 2016 Mirena Label
53. Deborah I. Friedman, *Medication-Induced Intracranial Hypertension in Dermatology*, 6 Am. J. Clinical Dermatology 29 (2005).
54. Deborah I. Friedman, *Idiopathic Intracranial Hypertension*, 11 Current Pain & Headache Rep. 62 (2007)
55. FDA Approval Package for Levaquin (Ross Dep. Ex. 10)

56. Listing of Adverse Event Reports from the WHO Uppsala Monitoring Centre
(Fraunfelder Dep. Ex. 3)
57. Listing of Adverse Event Reports from the WHO Uppsala Monitoring Centre
(Fraunfelder Dep. Ex. 8)

Dated: January 20, 2017

Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that on January 20, 2017, a copy of the foregoing was filed electronically via the Court's CM/ECF system, which will have sent notice to the following attorneys of record in this matter:

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